SYSTEM AUDIT REPORT NUMBER: 05/35812/AS-S05	nqa usa

THIS REPORT RELATES TO A/AN SURVEILLANCE VISIT ON November 1-4, 2005

Company: NASA, Marshall Space Flight Center	**Other Sites Visited:** **1.**
Address: MSFC Huntsville, AL 35812	**2.**

Scope:

ISO 9001:2000: All Products and Services Provided by the Marshall Space Flight Center. MSFC Supports the NASA Agency Infrastructure and is a Major Contributor to All Its Scientific and Technical Enterprises.

AS9100: Design, Development, Production, Installation and Servicing of Flight Hardware, Flight Software, and associated Ground Support Equipment Interfacing with Flight Hardware and Fight Software.

Standard(s): 9001:2000/AS9100B	**Support Documentation(s):** AS9101B	**Non-English Languages Used:**

Comments/Concerns of the Assessment Team:

Previously identified non-compliances have been satisfactorily addressed or rewritten herein. (items 1&2)
Non-compliances are minor in nature

The visit is deemed to be:	**Corrective Action Plan (CAP) Instructions:**
x☐ **Satisfactory** ☐ **Unsatisfactory**	☐ Return CAP in 20 working days (all NCs, Obs & OIs). Certificate processing initiates after receipt/acceptance of CAPs.
Unsatisfactory visits may result in a change to the next audit activity.	☐ AS & QS-9000 NCs must be closed prior to certificate issuance. ☐ Return CAP in ten days for Major NCs issued during surveillance.

NQA ASSESSMENT TEAM		**COMPANY INFORMATION**
LEAD AUDITOR: Rick Giguere		MGT. REP.: Robin Henderson
TEAM:	TEAM:	QUALITY MANUAL (REV & ISSUE DATE):Rev N 9/17/04
TEAM:	TEAM:	

NQA, USA Representative Signature and Date:	Company Representative Signature and Date:	
Rick Giguere 11/4/05	Robin M. Henderson 11/4/05	

SYSTEM AUDIT REPORT NUMBER: 05/35812/AS-S06

nqa usa

AUDIT MATRIX

X or √ through entire box as applicable to indicate actual function/process audited against the AS9100 requirement. X or √ in next visit block indicates planned section for next activity. Estimated duration is 45 minutes. Note: Asterisk (*) indicates requirement to be reviewed at each activity.

AS9100 Reference	Clause Title	SPECIFIC AS9100 REQUIREMENTS FUNCTIONS/PROCESSES AUDITED DURING THIS VISIT															NEXT VISIT PLAN
		HEI - Quality	QD-40 Audits	MSRR-1 SW	MSRR-1 HW	QD02 PMC	Test Services	QD 30	HS 20 / 40	QD 40 - 50	MQC/IMSB	UNITes IT					
4.2.1 & 4.2.2*	Quality Manual *																X
4.2.3	Document Control																X
4.2.4	Quality Records	X	X		X	X	X		X	X	X	X					X
4.3	Configuration Management				X		X										X
4.1, 5.1, 5.2, 5.3, 5.4.2, 5.5	Management Activities										X						
5.4.1*	Quality Objectives*					X					X						X
5.6*	Management Review *										X						X
6.1 & 6.2	Resources & Competence						X		X	X	X						
6.3 & 6.4	Infrastructure & Work Environment						X										
7.1	Product Realization Planning																
7.2	Customer Related Process & Comm.																
7.3	Design & Development			X	X												
7.4	Purchasing																
7.5.1 & 7.5.3	Process Provision and ID&T Activities						X	X									
7.5.2	Process Validation																
7.5.4	Customer Property																
7.5.5	Preservation (Handling, Storage & Deliv.)																
7.6	Calibration																
8.1	Measurement & Monitoring Planning																X
8.2.1*	Customer Satisfaction*										X						X
8.2.2*	Internal Audits*		X														X
8.2.3	Measurement &Monitoring of Process					X											X
8.2.4	Measurement & Monitoring of Product																X
8.3	Non-Conforming Processes/Products																X
8.4	Analysis of Data					X					X						X
8.5.1*	Continuous Improvement*										X						X
8.5.2 & 8.5.3*	Corrective/Preventive Action*	X										X					X
Use of NQA Logo*		X															X

Note: Please fill in the table including areas/sites/departments/functions visited during the visit.

SYSTEM AUDIT REPORT NUMBER 05/35812/AS-S06	nqa usa
SYSTEM AUDIT RECORD	
Auditor(s): Richard Giguere	**Date:** November 1 - 4, 2005

Clause No.	Record of Audit Details (names, reference documents, departments, etc.)	NC	Obs or OIs
4.2.2, 4.3, 5.4.1, 5.6	*See AS9101B Checklist for details* INTERVIEWED: DOCUMENTS REVIEWED: OBJECTIVE EVIDENCE SAMPLED:		
6.1, 6.2, 6.3, 6.4	*See AS9101B Checklist for details* INTERVIEWED: DOCUMENTS REVIEWED: OBJECTIVE EVIDENCE SAMPLED:		
7.3.1 - 7.3.6, 7.5.1, 7.5.3	*See AS9101B Checklist for details* INTERVIEWED: DOCUMENTS REVIEWED: OBJECTIVE EVIDENCE SAMPLED: 7.5.5, 7.6 were not reviewed in entirety. NC's were written against these requirements as carried from previous audit.	2	
8.2.1, 8.2.2, 8.2.3, 8.4, 8.5.1, 8.5.2/3	*See AS9101B Checklist for details* INTERVIEWED: DOCUMENTS REVIEWED: OBJECTIVE EVIDENCE SAMPLED:		1

TOTAL	2	1

SYSTEM AUDIT REPORT NUMBER 05/35812/AS-S06

nqa usa

Ref No.	Clause No.	NON-CONFORMANCES & OBSERVATIONS/OPPORTUNITIES FOR IMPROVEMENT RAISED	NC/OBS/ OI
1	7.5.5	MWI 8550.5, Hazardous Material Mgmt, states in part that hazardous material storage areas are to be regularly inspected for "leaking, severly corroded containers, and unneeded, out-of-shelf life products." A review of the contents of Flammable Content cabinets in vibration lab reveals age-sensitive materials well beyond the expiration date, some items by over 10 years. (Ref. S05 report.)	NC
2	7.6	The process for dealing with IM&TE that is found to be out of tolerance at calibration is not clearly established for users outside the calibration lab. MPR 8730.5 directs the user of out-of-tolerance devices to refer to MWI 1280.3 for instruction on actions to take, however, this procedure deals with processing Alerts, and no reference made to evaluating effect of OOT on product. (Ref. S05 Rpt)	NC
3	8.5.2	QD153/RCAR216 was initiated in Feb 2004 and last updated with a status in Feb 2005. Even though there has been ongoing activity on this corrective action, the database has no record of such activity, giving the appearance of no activity. A clearer picture of current status would be provided if actions were noted in the comments saction of the database, particularly for long-term actions.	OBS

NQA, USA Representative Signature and Date: 11/04/05

Company Representative Signature and Date: Robert M. Henderson 11/4/05

ASSESSMENT REPORT	*Assessing company logo*

GENERAL ASSESSMENT INFORMATION

1 Organization & Work Address

Company Name: NASA, Marshall Space Flight Center Subsidiary of: Organization Identification: Assessed Site Address: Huntsville, AL 35812 Main activities: Product Types or Codes:	Tel Number: 256-544-0451 Fax Number: 256-544-4155 e-mail: robin.henderson@msfc.nasa CAGE code: Assessment Representative & Title: Robin Henderson, Associate Director Quality Manager Representative & Title: Robin Henderson, Associate Director

2 ISO Registration

[ ] ISO Registered [x] ISO Standard / Revision ISO 9001:2000 [x] Aerospace Standard / Revision AS9100B	Registrar Name: NQA-USA Expiration Date (If applicable): May 27, 2007

3 Assessment Team

Lead Assessor Name: [x] Certified Auditor – Type & No. A03158 [ ] Qualified Auditor	Other Assessor Team Members:

4 Assessment Dates: November 1- 4, 2005

5 Assessment Scope

[ ] Total facility assessed	[ ] Initial assessment	[ ] All 9100 elements assessed
[x] Partial facility assessed	[ ] Re-assessment	[x] Partial 9100 elements assessed
[ ] Other:		Elements not assessed:
[ ] Activity assessed:		

6 Assessment Disposition	**7 Scoring**
[ ] Conforming	Scoring result: 97
[x] Conforming with minor (mi) corrective action	
[ ] Non conforming with Major (MA) corrective action	

8 Assessment Approval

Assessing Company	Date	Lead Assessor Name	Signature
NQA-USA	May 20, 2005	Richard Giguere	Rick Giguere

Distribution Agreement

This Assessment Report is the property of the assessed Organization and the assessing Company. Distribution to other companies or individuals is authorized only after written agreement of the assessed Organization and of the assessing Company.

To that end, a signature below by an Authorized Representative of the assessing company indicates that this report may be copied by the organization for other customers.

If copied, the report must be disclosed in full including findings and any corrective actions.

Authorized Representative
Assessing Company Name ___Richard Giguere____ Signature Rick Giguere Date 11/4/05

ASSESSMENT REPORT	*Assessing company logo*

ASSESSMENT CONCLUSIONS

General comments about the organization and the quality system of the assessed organization:

1. Good overall consistency of management system.

Strong points:

1. **Internal Audit Process, good reporting and audit tools**
2. **Scorecard approach to establishing alignment of NASA goals with MSFC objectives throughout organization**
3. **Ability to maintain integrity of QMS through change. (Transformation) You are managing change and not being managed by change.**

Improvement Opportunities:

1. **Be cautious to maintain record integrity over time and through personnel and system changes.**
2. **Be cautious to ensure all design review records are formally maintained and accessible.**

ASSESSMENT REPORT

Assessing company logo

ASSESSMENT RESULT SUMMARY

Organization : NASA, Marshall Space Flight Center

Elements* (AS9100 – Section 1)	Result S	Ma	mi	N/A	Observation / Corrective Action Request Number (MA/mi)
4 - Quality Management System					
4.1 General requirements	S				
4.2 Documentation requirements	S				
4.3 Configuration Management	S				
5 - Management responsibility					
5.1 Management commitment	S				
5.2 Customer focus	S				
5.3 Quality policy	S				
5.4 Planning	S				
5.5 Responsibility, authority and communication	S				
5.6 Management review	S				
6 - Resource managements					
6.1 Provision of resources	S				
6.2 Human resources	S				
6.3 Infrastructure	S				
6.4 Work environment	S				
7 - Product realization					
7.1 Planning of product realization	S				
7.2 Customer-related processes	S				
7.3 Design and development	S				
7.4 Purchasing	S				
7.5 Production and service provision			1		Carry Over
7.6 Control of monitoring and measuring devices			1		Carry Over
8 - Measurement, analysis and improvement					
8.1 General	S				
8.2 Monitoring and measurement	S				
8.3 Control of NC product	S				
8.4 Analysis of data	S				
8.5 Improvement	S				
Assessed Organization: NASA, Marshall Space Flight Ctr. Rep's name: Robert M. Henderson Signature:			2		Assessing Company: N Q A, USA
	Results				Lead Assessor Name: Richard Giguere Signature:

* For each element, cross results of assessment: "S" for Satisfactory, "Ma" for major corrective action, "mi" for minor or "N/A" for non applicable

ASSESSMENT SCORING

(Member logo)

Organization : NASA, Marshall Space Flight Ctr.

	SCORING CHART	Result					
		Major CAR or minor CAR on Key requirement		Minor CAR on **non** Key requirement		NO CAR	RESULT
		Multiple findings	Single finding	Multiple findings	Single finding		
4	**Quality management system**					(100)	100
4.1	General requirements	0	10	25	40	50	50
4.2 & 4.3	Documentation requirements & Configuration management	0	10	25	40	50	50
5	**Management responsibility**					(150)	150
5.1	Management commitment						
5.2	Customer focus	0	5	15	20	30	30
5.3	Quality policy						
5.4	Planning	0	10	20	30	40	40
5.5	Responsibility, authority and communication	0	5	15	20	30	30
5.6	Management review	0	10	25	40	50	50
6	**Resource Management**					(100)	100
6.1	Provision of resources	0	10	25	40	50	50
6.2	Human resources						
6.3	Infrastructure	0	10	25	40	50	50
6.4	Work environment						
7	**Product realization**					(450)	
7.1	Planning of product realization	0	5	15	20	30	30
7.2	Customer related processes	0	10	30	50	60	60
7.3	Design and development						
7.3.1	*D& D Planning*	0	5	15	20	30	30
7.3.2-3-4	*Inputs, outputs & review*	0	5	15	20	30	30
7.3.5-6	*D&D verification & validation*	0	5	15	20	30	30
7.3.7	*Control of design and development changes*	0	5	15	20	30	30
7.4	Purchasing	0	10	30	50	60	60
7.5	Product and service provision						
7.5.1	*Control of production and service provision*	0	10	25	40	50	50
7.5.2	*Validation of processes for production and service provision*	0	10	20	30	40	40
7.5.3	*Identification and traceability*	0	10	20	30	40	40
7.5.4-5	*Customer property & preservation of product*	0	5	15	20	30	5
7.6	Control of monitoring and measuring device	0	5	10	15	20	15
8	**Measurement analysis and improvement**					(200)	200
8.1	General	0	5	10	15	20	20
8.2	Monitoring and measurement						
8.2.1	*Customer satisfaction*	0	5	10	15	20	20
8.2.2	*Internal audit*	0	5	15	20	30	30
8.2.3	*Monitoring and measurement of processes*	0	5	15	20	30	30
8.2.4	*Monitoring and measurement of product*	0	5	15	20	30	30
8.3	Control of nonconforming product	0	5	15	20	30	30
8.4	Analysis of Data	0	5	10	15	20	20
8.5	Improvement	0	5	10	15	20	20
					TOTAL	880 (1) or 1000	970
					SCORE	97/ 100	

The assessed Organization agrees on the Quality System scoring and Corrective Action requests		
Organization Representative :	Signature : Robin M. Henderson	Date : 11/4/05

(1) When 7.3 is not assessed : SCORE = $\frac{\text{RESULT X 100}}{880}$

QUALITY SYSTEM QUESTIONNAIRE						
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E	

4 QUALITY MANAGEMENT SYSTEM

4.1 General requirements

01 Has the organization established, documented, implemented and maintained a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard ?						
02 Does the organization : a) identify the processes needed for the quality management system and their application throughout the organization (1) ? b) determine the sequence and interaction of these processes (1) ? c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective ? d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes ? e) monitor, measure and analyze these processes ? and f) implement actions necessary to achieve planned results and continual improvement of these processes ?						
03 Are these processes managed by the organization in accordance with the requirements of this International Standard ?						
04 Where an organization chooses to outsource any process that affects product conformity with requirements, does the organization ensure control over such processes ?	P					
05 Is the control of such outsource processes identified within the quality management system ?						

Note : Processes needed for the quality management system referred to above should include processes for management, provision, product realization and measurement.

Guidance Note

1) Main process formally identified e.g. : list, flow diagram, etc.

Objective evidence assessed / Observations / Comments / N/A explanation

S: Satisfactory - CAR: Corrective action required – Ma: Major corrective action – mi: Minor corrective action
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

4.2 Documentation requirements

4.2.1 General

06 Does the quality management system documentation include : a) documented statements of a quality policy and quality objectives ? b) a quality manual ? c) documented procedures required by this International Standard ? d) documents needed by the organization to ensure the effective planning, operation and control of its processes ? e) records required by this International Standard (see 4.2.4) ? and ***f) quality system requirements imposed by the applicable Regulatory Authorities ?***		✓			
07 Does the organization ensure that personnel have access to quality management system documentation and are aware of relevant procedures ?		✓			
08 Do Customer and/or regulatory authority representatives have access to quality management system documentation ?		✓			

4.2.2 Quality manual Rev N - 9/17/04

09 Has the organization established and maintained a quality manual that includes (1) : a) the scope of the quality management system, including details of, and justification for, any exclusions ? b) the documented procedures established for the quality management system, or reference to them, and ***when referencing the documented procedures, is the relationship between the requirements of this International Standard and the documented procedures clearly shown (2) ?*** c) a description of the interaction between the processes of the quality management system ?		✓			

Note 1 : Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.
Note 2 : The extent of the quality management system documentation can differ from one organization to another due to
a) the size of organization and type of activities,
b) the complexity of processes and their interactions, and
c) the competence of personnel

Guidance Notes
1) Quality manual reference and issue
2) Check the procedure list

Objective evidence assessed / Observations / Comments / N/A explanation

Reviewed proposed change to Manual - including proposed update to Quality Policy to reflect new NASA Values

Observed QMS documentation primarily electronic version -
- reviewed policy + objectives
- assorted documents as needed by functional area + accessible at POC.
- assorted records as noted herein
- access to QMS is available

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

4.2. Documentation requirements (continued)

4.2.3 Control of documents					
10 Are the documents required by the quality management system controlled ?	M				
11 Are records controlled according to the requirements given in 4.2.4 ?					
12 Has a documented procedure been established to define the controls needed to : a) approve documents for adequacy prior to issue ? b) review and update as necessary and re-approve documents ? c) ensure that changes and the current revision status of documents are identified ? d) ensure that relevant versions of applicable documents are available at points of use ? e) ensure that documents remain legible and readily identifiable ? f) ensure that documents of external origin are identified and their distribution controlled ? and g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose ?					
13 Does the organization coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements ?					✓
4.2.4 Control of records					
14 Are records established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system ?					
15 Do records remain legible, readily identifiable and retrievable (1) ?					
16 Has a documented procedure been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records ?					
17 Does the documented procedure define the method for controlling records that are created by and/or retained by suppliers ?					
18 Are records available for review by customers and regulatory authorities in accordance with contract or regulatory requirements ?					✓
4.3 Configuration management					
19 Has the organization established, documented and maintained a configuration management process appropriate to the product ?	P	✓			

Guidance Note

1) List records reviewed

Objective evidence assessed / Observations / Comments / N/A explanation

Reviewed Dwgs & the documents for proper confis

TAS - 302 - 1001 Rev X4

TSS - 300 - 5 Rev B1

TPS - 300 - 1180 - M

TPS - 300 - 1138 - M

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
5 MANAGEMENT RESPONSIBILITY					
5.1 Management commitment					
01 Has Top management provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by (1) : a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements ? b) establishing the quality policy ? c) ensuring that quality objectives are established ? d) conducting management reviews ? And e) ensuring the availability of resources ?	M	✓			
5.2 Customer focus					
02 Has Top management ensured that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1) ?		✓			
5.3 Quality policy					
03 Has Top management ensured that the quality policy : a) is appropriate to the purpose of the organization ? b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system ? c) provides a framework for establishing and reviewing quality objectives ? d) is communicated and understood within the organization (2) ? and e) is reviewed for continuing suitability ?		✓			
5.4 Planning					
5.4.1 Quality objectives					
04 Has Top management ensured that quality objectives, including those needed to meet requirements for product [see 7.1 a)] are established at relevant functions and levels within the organization (3) ?		✓			
05 Are the quality objectives measurable and consistent with the quality policy ?	M	✓			
5.4.2 Quality management system planning					
06 Has Top management ensured that : a) the planning of the quality management system is carried out in order to meet the requirements (see 4.1), as well as the quality objectives ? and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented ?		✓			

Guidance Notes

1) Evidence of management commitment
2) Identify and records method of communication
3) Review objectives and status of their implementation

Objective evidence assessed / Observations / Comments / N/A explanation

Observed Management Commitment to QMS + improvement through involvement in Integrated Mgmt Syst. Board (ISMB) and Program/Project Mgmt Council (PMC)
Discussed Customer focus (satisfaction) issues / perspective + associated measures.
Reviewed Policy change – Marshall/NASA values + integration with objectives using scorecard approach.
Observed integrity of QMS through change (Transformation)

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
5.5 Responsibility, authority and communication					
5.5.1 Responsibility and authority					
07 Has Top management ensured that the responsibilities and authorities are defined and communicated within the organization (1) ?					✓
5.5.2 Management representative					
08 Has Top management appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes : a) ensuring that processes needed for the quality management system are established, implemented and maintained ? b) reporting to top management on the performance of the quality management system and any need for improvement ? c) ensuring the promotion of awareness of customer requirements throughout the organization ? and ***d) the organizational freedom to resolve matters pertaining to quality ?***	M				✓
5.5.3 Internal communication					
09 Has Top management ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system ?					✓

Guidance Note

1) Identify and records method of communication within the organization

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
5.6 Management review					
5.6.1 General					
10 Has Top management reviewed the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness (1) ?		✓			
11 Does this review include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives ?		✓			
12 Are records from management reviews maintained (see 4.2.4) ?		✓			
5.6.2 Review input					
13 Does the input to management review include information on (2) : a) results of audits? b) customer feedback? c) process performance and product conformity? d) status of preventive and corrective actions? e) follow-up actions from previous management reviews? f) changes that could affect the quality management system? And g) recommendations for improvement?	M	✓			
5.6.3 Review output					
14 Does the output from the management review include any decisions and actions related to (2) : d) improvement of the effectiveness of the quality management system and its processes? e) improvement of product related to customer requirements? And f) resource needs?	M	✓			

Guidance Notes

1) Records management review frequency and functions involved (e.g : quality, production, etc.)
2) Verify the availability of input / output data such as: statistical data; graphics; summary tables; reports; etc.

Objective evidence assessed / Observations / Comments / N/A explanation

IMSB - 10/25/05 - Resource Mfg Minutes, Presentation Package
- Customer feedback -
- Objectives - flowdown of goals/objectives throughout org. ← RACI
  - ~~Balanced~~ Center Scorecard approach -.
  - alignment throughout org.
- audit Results - NCRs - Tracking/Trending
- Process Perf./Prod Conf. - PMC metrics - Schedule, Cost, Technical, Mgmt
  - Mgmt Directive status
- CA/PA - RCARs, Recurrence Control, GIDEP Alerts, Prev Actions
- Changes - IEMP; EMS implementation, changes to Agency Directives
- Q Policy Changes also observed PMC data from 10/25/05 (see 8.4)

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***N/A**: Not applicable - **N/E**: Not evaluated - **P**: Product - **M**: Management*

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
6. RESOURCE MANAGEMENT					
6.1 Provision of resources					
01 Has the organization determined and provided the resources needed: a) to implement and maintain the quality management system and continually improve its effectiveness ? And b) to enhance customer satisfaction by meeting customer requirements ?		✓			
6.2 Human resources					
6.2.1 General					
02 Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience (1) ?		✓			
6.2.2 Competence, awareness and training Competency Mgmt System					
03 Does the organization : a) determine the necessary competence for personnel performing work affecting product quality (2) ? b) provide training or take other actions to satisfy these needs ? c) Evaluate the effectiveness of the actions taken ? d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives ? e) maintain appropriate records of education, training, skills and experience (see 4.2.4) (3) ?	P	✓			
6.3 Infrastructure					
04 Does the organization determine, provide and maintain the infrastructure needed to achieve conformity to product requirements ? Infrastructure includes, as applicable : a) buildings, workspace and associated utilities ? b) process equipment (both hardware and software) ? And c) supporting services (such as transport or communication) ?		✓			
6.4 Work environment					
05 Does the organization determine and manage the work environment needed to achieve conformity to product requirements ?	P	✓			

Note : Factors that may affect the conformity of the product include temperature, humidity, lighting, cleanliness, protection from electrostatic discharge, etc.

Guidance Notes

1) Review training Records and Plan (status of the current year and of the previous year)
2) Give examples of methods used to determine competence (e.g.: competence matrix, multiskill,....)
3) Review training certificates for the certified personnel and training records (internal and external training courses)

Objective evidence assessed / Observations / Comments / N/A explanation

Certification - per MWI 3410.1 - Rev E.

Notes continued on Next page

Personnel Certification - D. Eckstein

CERTRAK - James Babicz -

Competency Management System - CMS-DOC-01 Rev 5a.

- Determination of Critical Competencies - E. Johnson - Flight syst. Eng.
- - L. Coe - Elect. Instrumentation Spt.
- Maintains record of Training -

Observed Infrastructure at Test - Work environment - Hazardous Material Handling

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Reviewed evaluation of Competency - 24 Rated as Fails to Meet, Meets & Exceeds & Distinguished
100% evaluated.

QUALITY SYSTEM QUESTIONNAIRE ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7. PRODUCT REALIZATION					
7.1 Planning of product realization					
01 Does the organization plan and develop the processes needed for product realization ? (see 4.1)					✓
02 Is planning of product realization consistent with the requirements of the other processes of the quality management system (see 4.1) ?					✓
03 In planning product realization, does the organization determine the following, as appropriate : a) quality objectives and requirements for the product ? b) the need to establish processes, documents, and provide resources specific to the product ? . c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance ? d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) ? e) ***the identification of resources to support operation and maintenance of the product ?***	P				✓
04 Is the output of this planning in a form suitable for the organization's method of operations?					✓

Objective evidence assessed / Observations / Comments / N/A explanation

6.1-6.4

Notes continued from previous page

Certifications – { J. Webster – Explosive Handler cert.
w/o T-2386-SPT2388M – { M. Vanderbeir – " "

w/o T-2415-1152939 – S. McMyler – Cryogen Handler certification
M. Vanderbeir – " "

Mandatory Training – IT Security
– EMS Training
} Sampled 4 files

S: Satisfactory - CAR: Corrective action required – Ma: Major corrective action – mi: Minor corrective action
N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

05 Does the organization determine : a) requirements specified by the customer, including the requirements for delivery and post-delivery activities ? b) requirements not stated by the customer but necessary for specified or intended use, where known ? c) statutory and regulatory requirements related to the product ? and d) any additional requirements determined by the organization ?	M				✓

7.2.2 Review of requirements related to the product

06 Does the organization review the requirements related to the product ?					✓
07 Is the review conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and does it ensure that (1) : a) product requirements are defined ? b) contract or order requirements differing from those previously expressed are resolved ? c) the organization has the ability to meet the defined requirements ? ***And*** ***d) risks (e.g., new technology, short delivery time scale) have been evaluated ?***	P				✓
08 Are records of the results of the review and actions arising from the review maintained (see 4.2.4) (2) ?					✓
09 Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organization before acceptance ?					✓
10 Where product requirements are changed, does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements ?	P				✓

Note : In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover the relevant product information such as catalogues or advertising material.

7.2.3 Customer communication

11 Does the organization determine and implement effective arrangements for communicating with customers in relation to : a) product information ? b) enquiries, contracts or order handling, including amendments ? and c) customer feedback, including customer complaints ?					✓

Guidance Notes

1) Check that all affected functions are involved in the review
2) Give examples

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.3 Design and development					
7.3.1 Design and development planning					
12 Does the organization plan and control the design and development of product ?		✓			
13 During the design and development planning, does the organization determine :	M				
a) the design and development stages (1) ? ✓					
- *in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,* Prgm Plan		✓			
b) the review, verification and validation that are appropriate to each design and development stage ? and					
c) the responsibilities and authorities for design and development ?					
14 Where appropriate, due to complexity, does the organization give consideration to the following activities :					
- ***structuring the design effort into significant elements ?***		✓			
- ***for each element, analyzing the tasks and the necessary resources for its design and development. Does This analysis consider an identified responsible person, design content, input data, planning constraints, and performance conditions. Is the input data specific to each element reviewed to ensure consistency with requirements ?***					
15 Does the organization manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility ?		✓			
16 Is planning output updated, as appropriate, as the design and development progresses ?		✓			
17 Are the different design and development tasks to be carried out defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements (2) ?	P	✓			
7.3.2 Design and development inputs					
18 Are inputs relating to product requirements determined and are records maintained (see 4.2.4) (3) ?	M				
Do these inputs include :					
a) functional and performance requirements ? ✓		✓			
b) applicable statutory and regulatory requirements ? ✓					
c) where applicable, information derived from previous similar designs ? and ✓					
d) other requirements essential for design and development ? ✓					
19 Are these inputs reviewed for adequacy ? Code reviews / peer reviews		✓			
20 Are requirements completed, unambiguous and not in conflict with each other ?		✓			

Guidance Notes

1) Give at least an example of a completed design & development plan, or an example of one in progress, that identifies the planning of tasks and key events.
2) Give an example
3) Review applicable input data (give examples)

Objective evidence assessed / Observations / Comments / N/A explanation

MSSR Project - EI32-OI-001 Rev P
Material Science Research Branch -
MSFC-PLAN-3076 - Rev D
MSRR-1-DOC-0001 12/1/03 - Concept Document
SRS - (MSFC-SPEC-2986) Rev C July 05
includes Software Reqts Traceability Matrix of derived reqts

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PM - System Design

7.3.1 inputs - MSRR-1 (SRED) MSFC-RQMT-2994

planning doc. MSFC-PLAN-2902 4/2/03

Proj. schedule - OK

open action status reporting

Monthly Status 10/19/05 MSRR-1

- Inputs - MSFC-RQMT-2871 Rev D 8/5/05

- Des. Reqt's flowdown as defined in MSFC-RQMT-2994

Par 4.2.2.3.1 Processing Timeline under Funct. & Performance Reqt's (4.2.2.3)

Verification Reqt's established with specified criteria TCP

⇒ Board minutes to authorize progression to next stage (CDR) OK

see - Pre Board Mtg for CDR 6/17/02

Plan 2902 - states -

Proj. Level Reviews will be conducted periodically w/ proj team -

with MSAD Mgr.

QUALITY SYSTEM QUESTIONNAIRE ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.3 Design and development (continued)

7.3.3 Design and development outputs					
21 Are the outputs of design and development provided in a form that enables verification against the design and development input and approved prior to release ? Reqts Traceability Matrix		✓			
22 Do the design and development outputs : a) meet the input requirements for design and development ? b) provide appropriate information for purchasing, production and for service provision ? c) contain or reference product acceptance criteria ? d) specify the characteristics of the product that are essential for its safe and proper use ? ***and*** ***e) identify key characteristics, when applicable, in accordance with design or contract requirements ?***	M	✓			
23 Is all pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained defined by the organization; for example: ***- drawings, part lists, specifications ?*** ***- a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product ?*** ***- information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product ?***	M	✓			
7.3.4 Design and development review					
24 At suitable stages, are systematic reviews of design and development performed in accordance with planned arrangements (see 7.3.1) to (1) : a) evaluate the ability of the results of Design and development to meet requirements ? b) identify any problems and propose necessary actions ? ***and*** ***c) authorize progression to the next stage ?***	M	✓			
25 Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed ?		✓			
26 Are records of the results of the reviews and any necessary actions maintained (see 4.2.4) ?		✓			
7.3.5 Design and development verification					
27 Is verification performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements ?		✓			
28 Are records of the results of the reviews and any necessary actions maintained (see 4.2.4) ?		✓			

Note : **Design and/or development verification may include activities such as :**
- **performing alternative calculations**
- **comparing the new design with a similar proven design, if available**
- **undertaking tests and demonstrations, and**
- **reviewing the design stage documents before release.**

Guidance Notes

1) Give evidence of reviews

Objective evidence assessed / Observations / Comments / N/A explanation See additional pages

MSRR - Laptop Rebound Hdy - SRR conducted June 30, 05

MSRR-1-SRR-013 Status of RIDs (action items)

SWPDR 3/30/99
SW CDR 2/02
TRR - 8/25/04

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MSRR-1 Software Dev.

7.3.3

EI32-OI-001 par 10.1.6.x PSD output

10.1.6.2 • development of Prelim SDD ✓ verified

10.1.6.3 { • RID Progress
{ • Code Progress

10.1.7 • all RIDs closed prior to Detailed S.D. phase ✓

Par 10.2.3 SW Des. Desc. Task Resp.

• Des. Walk-through +/or Peer Review of SW detail Des.

• Define CSCI components. ✓

• SW item input/output descriptions ✓

Par 10.2.6.1 - Metrics - code Prog; RID Prog., Defect Agging, Defect Density

10.2.6.2 ~~MSFC~~ - Detailed SDD - ED14-MSRR-DSDS Nov 7, '00 ✓

7.3.4

Verif Val phase

TRR - Aug 25, 2004

• Informal Test Status

⇒ • Mtg minutes
DAR - Submitted
DAR - W-04-1657

⇒ Peer Rev. example -

PB 28A

QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.3 Design and development (continued)

7.3.6 Design and development validation					
29 Is design and development validation performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known ?	P				✓
30 Wherever practicable, is validation completed prior to the delivery or implementation of the Product ?					✓
31 Are records of the results of validation and any necessary actions maintained (see 4.2.4) ?					✓

Note:
- Design and/or development validation follows successful design and/or development verification.
- Validation is normally performed under operating conditions.
- Validation is normally performed on the final product, but may be necessary in the earlier stages prior to product completion.
- Multiple validations may be performed if there are different intended uses.

7.3.6.1 Documentation of design and/or development verification and validation					
32 At the completion of design and/or development, does the organization ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions?	M				✓
7.3.6.2 Design and/or development verification and validation testing					
33 Where tests are necessary for verification and validation, are these tests planned, controlled, reviewed, and documented to ensure and prove the following (1) : *a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria ?* *b) test procedures describe the method of operation, the performance of the test, and the recording of the results ?* *c) the correct configuration standard of the product is submitted for the test ?* *d) the requirements of the test plan and the test procedures are observed ?* *e) the acceptance criteria are met ?*	P				✓

Guidance Note

1) Give an example of a qualification report

Objective evidence assessed / Observations / Comments / N/A explanation

MSRR-1-MSL-LPTP Test - records - inspected - Verified. SQA — Not to validation plan yet.

Software CM plan developed per EI32-OI-001 RevB

EI32-MSRR-1-CM RevB

⇒ SW Config Audit 18/OCT/05

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.3 Design and development (continued)					
7.3.7 Control of design and development changes					
34 Are design and development changes identified and records maintained ?					✓
35 Are the changes reviewed, verified and validated, as appropriate, and approved before implementation (1) ?	P				✓
36 Does the review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered ?	P				✓
37 Does the organization's change control process provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement ?					✓
38 Records of the results of the review of changes and any necessary actions maintained (see 4.2.4) ?					✓

Guidance Note

1) Give an example

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.4 Purchasing					
7.4.1 Purchasing process					
39 Does the organization ensure that purchased product conforms to specified purchase Requirements ?	P				
40 Is the type and extent of control applied to the Supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product ?					
41 Is the organization responsible for the quality of all products purchased from suppliers, including customer-designated sources ?					
42 Does the organization evaluate and select Suppliers based on their ability to supply product in accordance with the organization's requirements ?					
43 Are criteria for selection, evaluation and re-evaluation established ?					
44 Are records of the results of evaluations and any necessary actions arising from the evaluation maintained (see 4.2.4) ?					
45 Does the organization : ***a) Maintain a register of approved Suppliers that includes the scope of the approval (1) ?*** ***b) Periodically review Suppliers performance and use the records of these reviews as a basis for establishing the level of controls to be implemented (2) ?*** ***c) Define the necessary actions to take when dealing with Suppliers that do not meet requirements ?*** ***d) Ensure where required that both the organization and all Suppliers use customer-approved special process sources ?*** ***e) Ensure that the function having responsibility for approving Supplier quality systems has the authority to disapprove the use of sources ?***	M				

Guidance Notes

1) Review current list of approved Suppliers
2) Review suppliers performance / measurement system (e.g.: supplier rating, etc.)

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.4 Purchasing (continued)					
7.4.2 Purchasing information					
46 Does purchasing information describe the product to be purchased, including where appropriate (1) : *a) requirements for approval of product, procedures, processes and equipment ?* *b) requirements for qualification of personnel ?* *c) quality management system requirements ?* ***d) the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data ?*** ***e) requirements for design, test, examination, inspection and related instructions for acceptance by the Organization ?*** ***f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing ?*** ***g) requirements relative to :*** ***- supplier notification to Organizationr of nonconforming product ? and*** ***- arrangements for Organizationr approval of supplier nonconforming material ?*** ***h) requirements for the supplier to notify the Organization of changes in product and/or process definition and, where required, obtain organization approval ?*** ***i) right of access by the organization, their customer, and authorities to all facilities involved in the order and to all applicable records ? and*** ***j) requirements for the supplier to flow down to subtier suppliers the applicable requirements in the purchasing documents, including key characteristics where required ?***	P				
47 Does the organization ensure the adequacy of specified purchase requirements prior to their communication to the supplier ?					✓

Guidance Note

1) Examine purchase orders that apply to several types of procurement.

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.4 Purchasing (continued)

7.4.3 Verification of purchased product					
48 Does the organization establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements, they may include ***obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control, inspection and audit at supplier's premises, review of the required documentation, inspection of products upon receipt, and, delegation of verification to the supplier, or supplier certification*** ?	P				
49 Is purchased product held until it has been verified as conforming to specified requirements unless it is released under positive recall procedure ?					
50 Where the organization utilizes test reports to verify purchased product, is the data in those reports acceptable per applicable specifications (1) ?					
51 Does the organization periodically validate test reports for raw material (1) ?					
52 Where the organization delegates verification activities to the supplier, are the requirements for delegation defined and a register of delegations maintained (1) ?					
53 Where the organization or its customer intends to perform verification at the supplier's premises, does the organization state the intended verification arrangements and method of product release in the purchasing information ?					
54 Where specified in the contract, is the customer or the customer's representative afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements ?					
55 It is ensured that verification by the customer is not used by the organization as evidence of effective control of quality by the supplier (it does not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer) ?					

Guidance Note

1) Give an example

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.5 Production and service provision

7.5.1 Control of production and service provision

56 Does planning consider, as applicable : - ***the establishment of process controls and development of control plans where key characteristics have been identified*** - ***the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization*** - ***the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and*** - ***special processes (see 7.5.2).***	P		✓			
57 Does the organization plan and carry out production and service provision under controlled conditions (1). Do these controlled conditions include, as applicable : a) the availability of information that describes the characteristics of the product ? b) the availability of work instructions, as necessary ? c) the use of suitable equipment ? d) the availability and use of monitoring and measuring devices ? e) the implementation of monitoring and measurement ? f) the implementation of release, delivery and post-delivery activities ? ***g) accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product) ?*** ***h) evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized ?*** ***i) provision for the prevention, detection, and removal of foreign objects ?*** ***j) monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality ? and*** ***k) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations) ?***	 P P		✓			

Guidance Notes

1) List the Part Number(s) used for this review

Objective evidence assessed / Observations / Comments / N/A explanation

In Test area reviewed Dwgs, & TPS

Dwg: TAS-302-1061 Rev XX TPS-300-1180-M

TSS-300-5 Rev B1 300-1138M

Test Service Mgmt - Discussed Performance Measures - Sched, Cost, Perf. - Customer SAT - Resource considerations - competency Reqts, physical infrastructure -

- Test Eng.
- operator - control Tech
- Control Syst. Eng.

Test operation per 304-TCP-011 dated 11/3/05
P2509-LH2 Ice Frost Ramp

Control of Equipment, utilities, supplies, chemicals, Prevention of FOD,

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.5 Production and service provision (continued)					
7.5.1.1 Production documentation					
58 Are production operations carried out in accordance with approved data ?		✓			
59 Does the data contain as necessary : *a) drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1) ? and* *b) a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use ?*	P	✓			
7.5.1.2 Control of production process changes					
60 Are persons authorized to approve changes to production processes identified (1) ?	M				✓
61 Has the organization identified and obtained acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements ?					✓
62 Are changes affecting processes, production equipment, tools and programs documented ?	P				✓
63 Are procedures available to control their implementation ?					✓
64 Are the results of changes to production processes assessed to confirm that the desired effect has been achieved without adverse effects to product quality ?	P				✓
7.5.1.3 Control of production equipment, tools and numerical control (N.C.) machine programs					
65 Are production equipment, tools and programs validated prior to use and maintained and inspected periodically according to documented procedures ?	P				✓
66 Does validation prior to production use include verification of the first article produced to the design data/specification ?	P				✓
67 Are storage requirements, including periodic preservation/condition checks, established for production equipment or tooling in storage ?					✓
7.5.1.4 Control of work transferred, on a temporary basis, outside the organization's facilities					
68 When planning to temporarily transfer work to a location outside the organization's facilities, does the organization define the process to control and validate the quality of the work ?	M				✓

Guidance Notes

1) Clearly defined list or procedures

Objective evidence assessed / Observations / Comments / N/A explanation

Reviewed dwgs - TAS-302-T001 Rev XX
TSS-300-5 Rev B
TSP's - 300-1180-M
300-1138-M

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.5 Production and service provision (continued)

7.5.1.5 Control of service operations						
69 Where servicing is a specified requirement, do service operation processes provide for :						✓
a) a method of collecting and analyzing in-service data ?						
b) actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements (1) (2) ?						
c) the control and updating of technical documentation ?						
d) the approval, control, and use of repair schemes (3) ? and,						
e) the controls required for off-site work (e.g., organization's work undertaken at the customer's facilities) ?						
7.5.2 Validation of processes for production and service provision						
70 Does the organization validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement (This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered) (4) ?	P					✓
Note : These processes are frequently referred to as special processes.						
71 Does validation demonstrate the ability of these processes to achieve planned results ?						✓
72 Has the organization established arrangements for these processes including, as applicable :	M					
a) defined criteria for review and approval of the processes ?						✓
-qualification and approval of special processes prior to use ?						
b) approval of equipment and qualification of personnel ?						
c) use of specific methods and procedures ?						
- control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto (5) ?						
d) requirements for records (see 4.2.4) ?						
e) and revalidation ?						

Guidance Notes

1) Review reports issued following visits to the customer (technical support). Comment on method of collection of in service data. Examine some investigation reports
2) Review evidence of implementation of corrective and preventive actions.
3) Review evidence of what has been assessed (e.g.: maintenance manual, repair manual, information to customer)
4) Verify the existence of list of special processes.
5) Give examples

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7.5 Production and service provision (continued)

7.5.3 Identification and traceability					
73 Where appropriate, has the organization identified the product by suitable means throughout product realization ?		✓			
74 Does the organization maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration ?	P	✓			
75 Has the organization identified the product status with respect to monitoring and measurement requirements ?		✓			
76 When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), does the organization establish and document controls for the media (1) ?		✓			
77 Where traceability is a requirement, does the organization control and record the unique identification of the product (see 4.2.4) ?					✓
78 According to the level of traceability required by contract, regulatory, or other established requirement, does the organization's system provide for (2) :	P				
a) identification to be maintained throughout the product life ?					
b) all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch ?					✓
c) in any assembly, the identity of its components and those of the next higher assembly to be traced?					
d) in any given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved ?					

Note: In some industry sectors, configuration management is a means by which identification and traceability is maintained.

7.5.4 Customer property					
79 Does the organization exercise care with customer property while it is under the organization's control or being used by the organization (3) ?					✓
80 Has the organization identified, verified, protected and safeguarded customer property provided for use or incorporation into the product ?					✓
81 Does the organization define methods to identify and record customer products that are lost, damaged or otherwise made unusable and report such to the customer ?					✓

Note: Customer property can include intellectual property, ***including customer furnished data used for design, production and/or inspection***.

Guidance Notes

1) Give examples of method(s) used
2) Give examples of traceability level applied (up and down)
3) Identify types of product supplied by the customer.

Objective evidence assessed / Observations / Comments / N/A explanation

MPR-8730.2 Rev E - Stamp Database

Annual Audit → stamp 44Q, 15Q, 59Q

W/O #T-2386-SPT2385M Explosive Handling Ops

W/O #T-2415-115293M - Cryogen Handling Ops

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.5 Production and service provision (continued)					
7.5.5 Preservation of product					
82 Does the organization preserve the conformity of product during internal processing and delivery to the intended destination ?					/
83 Does the preservation include identification, handling, packaging, storage and protection ?					/
84 Does preservation also apply to the constituent parts of a product ?					/
85 Does preservation of product also include, where applicable in accordance with product specifications and/or regulations, provisions for : ***a) cleaning ?*** ***b) prevention, detection and removal of foreign objects ?*** ***c) special handling for sensitive products ?*** ***d) marking and labeling including safety warnings ?*** ***e) shelf life control and stock rotation ?*** ***f) special handling for hazardous materials ?***	P		#1 mi NC		/
86 Does the organization ensure that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration ?					/

Objective evidence assessed / Observations / Comments / N/A explanation

NC item 1 is Carry over from 505

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N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.6 Control of monitoring and measuring devices					
87 Does the organization determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1) (1) ?	P				
88 Does the organization maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria ? ***Note : Monitoring and measuring devices include, but are not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.***	M				
89 Does the organization establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements ?					
90 Does the organization ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out ?					
91 Where necessary to ensure valid results, is measuring equipment : a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (2) ? b) adjusted or re-adjusted as necessary ? c) identified to enable the calibration status to be determined ? d) safeguarded from adjustments that would invalidate the measurement result ? e) protected from damage and deterioration during handling, maintenance and storage ? ***f) recalled to a defined method when requiring calibration ?***					
92 Does the organization assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements ?			NC#2		
93 Does the organization take appropriate action on the equipment and any product affected ?	P				
94 Are records of the results of calibration and verification maintained (see 4.2.4) ?					
95 When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed ?	P				
96 Is this undertaken prior to initial use and reconfirmed as necessary ?					

Guidance Notes

1) Review that the organization has a process for ensuring the capability of measurement system (e.g. Interval Analysis, Resolution Analysis, Gage Repeatable & Reproducibility, etc.)
2) Ensure the links to the recognized international / national standard.

Objective evidence assessed / Observations / Comments / N/A explanation

carry over NC #2 from 505

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

01 Does the organization plan and implement the monitoring, measurement, analysis and improvement processes needed (1) : a) to demonstrate conformity of the product ? b) to ensure conformity of the quality management system, and ? c) to continually improve the effectiveness of the quality management system ?	M				✓
02 Does this include determination of applicable methods, including statistical techniques, and the extent of their use ?					✓

Note : ***According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support :***

- ***design verification (e.g., reliability, maintainability, safety) ;***
- ***process control :***
  - ***selection and inspection of key characteristics;***
  - ***process capability measurements;***
  - ***statistical process control;***
  - ***design of experiment;***
- ***inspection – matching sampling rate to the criticality of the product and to the process capability ;***
- ***failure mode and effect analysis.***

Guidance Notes

1) Give examples of data

Objective evidence assessed / Observations / Comments / N/A explanation

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.2 Monitoring and measurement (continued)					
8.2.1 Customer satisfaction					
03 As one of the measurements of the performance of the quality management system, does the organization monitor information relating to customer perception as to whether the organization has met customer requirements (1) ?		✓			
04 Are the methods for obtaining and using this information determined?		✓			
8.2.2 Internal audit MPR 1280.6 Para G					
05 Does the organization conduct internal audits at planned intervals to determine whether the quality management system (2) : a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization? and b) is effectively implemented and maintained?	M	✓			
06 Is an audit program planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits?		✓			
07 Is the audit criteria, scope, frequency and methods defined?		✓			
08 Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process (3) ?		✓			
09 Does the organization ensure internal auditors do not audit their own work ?		✓			
10 Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) defined in a documented procedure ?		✓			
11 Do the management responsible for the areas being audited ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes ?	M	✓			
12 Do follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2) (4) ?		✓			
13 Are detailed tools and techniques developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements ?		✓			
14 Are the selected internal audit tools acceptable in measuring the effectiveness of the internal audit and overall organization performance ?		✓			
15 Do internal audits also meet contract and/or regulatory requirements ?		✓			

Guidance Notes

1) Give examples of how customer's satisfaction is measured, committed, and acted upon.
2) Review of audit plan (status of the previous year and progress of the current year).
3) Check the list of approved auditors.
4) Review type of audits (questionnaire, synthesis, circulation, request for corrective actions, corrective actions follow-up).

Objective evidence assessed / Observations / Comments / N/A explanation

Customer feedback CF397, 399.
Int audit schedule - Requirements Matrix
auditor Training + independence
NI 08200501 -
EO 08200501 - NCR - 750, 751, 748, 737
Audit Team - J. Hill, Sonya Hutchinson
Audit Plan - used checklists, communication of team members / AL to auditee -
Exit Briefing dated 8/11/05 -

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.2 Monitoring and measurement (continued)					
8.2.3 Monitoring and measurement of processes					
16 Does the organization apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes ?					✓
17 Do these methods demonstrate the ability of the processes to achieve planned results ?					✓
18 When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product ?					✓
19 In the event of process nonconformity, does the organization (1) : ***a) take appropriate action to correct the nonconforming process ?*** ***b) evaluate whether the process nonconformity has resulted in product nonconformity ? and*** ***c) identify and control the nonconforming product in accordance with clause 8.3 ?***	P				✓
8.2.4 Monitoring and measurement of product					
20 Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met ?	P				✓
21 Is this carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) ?					✓
22 When key characteristics have been identified, are they monitored and controlled ?	P				✓
23 When the organization uses sampling inspection as a means of product acceptance, is the plan statistically valid and appropriate for use ?					✓
24 Does the plan preclude the acceptance of lots whose samples have known nonconformities ?					✓
25 When required, is the plan submitted for customer approval ?					✓
26 Is product held until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities ?	P				✓
27 Is evidence of conformity with the acceptance criteria maintained ?					✓
28 Do records indicate the person(s) authorizing release of product (see 4.2.4) ?					✓
29 Is product release and service delivery held until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer ?					✓

Guidance Note

1) Give examples of non conformity (product, process, ...).

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.2 Monitoring and measurement (continued)					
8.2.4.1 Inspection documentation					
30 Are measurement requirements for product or service acceptance documented ?					/
31 Does this documentation, which may be part of the production documentation, include : *a) Criteria for acceptance and/or rejection ?* *b) Where in the sequence measurement and testing operations are performed ?* *c) a record of the measurement results ? and* *d) type of measurement instruments required and any specific instructions associated with their use ?*	P				/
32 Do test records show actual test results data when required by the specification or acceptance test plan ?					/
33 When required to demonstrate product qualification does the organization ensure that records provide evidence that the product meets the defined requirements ?					/
8.2.4.2 First article inspection					
34 Does the organization's system provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result (1) ?	P				/

Guidance Note

1) Give examples of first article (new product and change).

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

8.3 Control of nonconforming product

Note: The term "nonconforming product" includes nonconforming product returned from a customer.

35	Does the organization ensure that product which does not conform to requirements is identified and controlled to prevent its unintended use or delivery ?	P				
36	Are the controls and related responsibilities and authorities for dealing with nonconforming product defined in a documented procedure ?					
37	***Does the organization's documented procedure define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions ?***					
38	Does the organization deal with nonconforming product in one or more of the following ways by: a) taking action to eliminate the detected nonconformity ? b) authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer ? c) taking action to preclude its original intended use or application ?	P				
39	***Does the organization prevent dispositions of use-as-is or repair, unless specifically authorized by the customer, if*** ***- the product is produced to customer design ? or*** ***- the nonconformity results in a departure from the contract requirements ?*** ***(Unless otherwise restricted in the contract, is organization-designed product, which is controlled via a customer specification, dispositioned by the organization as-use-as is or repair, provided the nonconformity does not result in a departure from customer-specified requirements ?)***					
40	***Is product dispositioned for scrap conspicuously and permanently marked, or positively controlled, until physically rendered unusable ?***	P				
41	Are records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, maintained (see 4.2.4) ?					
42	When nonconforming product is corrected, is it subject to re-verification to demonstrate conformity to the requirements ?					
43	When nonconforming product is detected after delivery or use has started, does the organization take action appropriate to the effects, or potential effects, of the nonconformity ?	P				
44	***In addition to any contract or regulatory authority reporting requirements, does the organization's system provide for timely reporting of delivered nonconforming product that may affect reliability or safety ?***	P				
45	***Does notification include a clear description of the nonconformity, which includes as necessary, parts affected, customer and/or organization part numbers, quantity, and date(s) delivered ?***					

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QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

8.4 Analysis of data

46 Does the organization determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made ?	M				
47 Does this include data generated as a result of monitoring and measurement and from other relevant sources ?					
48 Does the analysis of data provide information relating to : a) customer satisfaction (see 8.2.1) (1) ? b) conformity to product requirements (see 7.2.1) ? c) characteristics and trends of processes and products including opportunities for preventive action ? And d) suppliers ?					

Guidance Note

1) Give examples and check how the organization measures the effectiveness.

Objective evidence assessed / Observations / Comments / N/A explanation

MSFC Prgm Mgmt Committee 10/28/05

MPR-7120.4 PMC
- metrics
- Prgm/Proj Status
- Formulation Request
- Baseline changes for proj.
- Detail Status PMC - Last Board Meeting - Annual Detail PMC
- Manpower utilization
- Reserve burn-down
- Risk Mgmt
- Schedule
- Tech & Prime Metric

Cost, Sched, Tech, Mgmt.

Action items tracked in database - Received / status opened / closed.

- Discovery & New Frontiers - Annual PMC
  - Prgm overview
  - current status
  - Summary
  - Action status

Cost, sched, Tech. Mgmt

Test Service Management
- Performance Measures
- Resource Consideration
- Customer Satisfaction

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QUALITY SYSTEM QUESTIONNAIRE

ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.5 Improvement					
8.5.1 Continual improvement					
49 Does the organization continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review ?		✓			
8.5.2 Corrective action MPR 1280.4e					
50 Does the organization take action to eliminate the cause of nonconformities in order to prevent recurrence (1) ?	P	✓			
51 Are Corrective actions appropriate to the effects of the nonconformities encountered ?		✓			
52 Is a documented procedure established to define requirements for : a) reviewing nonconformities (including customer complaints) ? b) determining the causes of nonconformities ? c) evaluating the need for action to ensure that nonconformities do not recur ? d) determining and implementing action needed ? e) recording of the results of the action taken (see 4.2.4) ? f) reviewing corrective action taken ? ***g) flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause ? and*** ***h) specific actions where timely and/or effective corrective actions are not achieved ?***		✓			
8.5.3 Preventive action					
53 Does the organization determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence (2) ? Risk Mgmt activities	M	✓			
54 Are preventive actions appropriate to the effects of the potential problems ? –		✓			
55 Is a documented procedure established to define requirements for : Qdoc Alert a) determining potential nonconformities and their causes ? b) evaluating the need for action to prevent occurrence of nonconformities ? c) determining and implementing action needed ? – d) recording of the results of the action taken (see 4.2.4) ? and e-post e) reviewing preventive action taken ? – Change Status to reflect Actions		✓			

Guidance Notes

1) Select a non-conforming part and use 52 a) through h) to check for effectiveness.
2) Select a non-conforming part and use 55 a) through e) to check for effectiveness.

Objective evidence assessed / Observations / Comments / N/A explanation

C/A - J. McPherson - (HEI) RCAR #234, 232, 221

QD 153 / RCAR 216 Last status note in database is 2/05 — Obs- OI

initiated 2/04

8.5.2 – Cust. Feedback CF 397, 399 — Risk Mgmt

8.5.3 – IMSB - Integrated Mgmt Sys Board - Reports on Alert

Alert 7567, 7726 Tracking database

8.5.2 C/A Supplier - A018033 - Swindstrand -

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Annex A
(informative)

Bibliography

ISO 9000: 2000	Quality management systems – Fundamentals and vocabulary
ISO 9001: 2000	Quality management systems – Requirements
ISO 19011	Guidelines for auditing quality systems
EN 9100 – Section 1	Aerospace series – Quality management systems – Requirements (based on ISO 9001: 2000)